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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,021	07/26/2002	Naomi L. Esmen	11146//10904	4924
7590 06/17/2004 Sidley Austin Brown & Wood Suite 3400 717 North Harwood Dallas, TX 75201			EXAMINER SAUCIER, SANDRA E	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/088,021	<b>Applicant(s)</b> ESMON ET AL.	
	<b>Examiner</b> Sandra Saucier	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 2-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-11,13-20 and 22-25 is/are rejected.
- 7) ☒ Claim(s) 12,21 and 26-33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date: _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/7/02</u>  | 6) <input type="checkbox"/> Other: _____                                    |

DETAILED ACTION

Claims 1–33 are pending. Claims 1, 7–33 are considered on the merits.

*Election/Restrictions*

Applicant's election of Group I in the reply filed on 5/12/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections – 35 USC § 112

INDEFINITE

Claims 1 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is an incomplete claim in that no step of assessing the propensity of patient risk for thrombotic disease as required by the preamble, is present in the body of the claim.

Claim 25 does not further limit claim 24.

SCOPE

Claims 1, 7, 8, 13–17, 22–25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining thrombotic disease risks or the presence of antibodies which selectively block the action of oxidized lipids, using an assay involving activated protein C and PE:PS:PC, does not reasonably provide enablement for determining such a risk using any and all clotting assays. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

nature of the invention

The invention is directed to determining risk of thrombotic disease by performing a coagulation assay with and without the presence of oxidized phospholipids containing PE and comparing the results.

breadth of the claims

The claims are directed to the performance of any coagulation test and require the use of a non-oxidized and oxidized phospholipid to determine patient risk for thrombotic disease.

amount of guidance and working examples

The specification clearly states that activated protein C is the target molecule that oxidized phospholipids act upon. Further, in Figure 1, it is shown that a difference in the clotting time is obtained only when activated protein C and oxidized and non-oxidized PE is present. A mixture of PS:PC and APC does not yield differences in clotting time with/without the presence of oxidized PS:PC. Therefore, the set of reagents used in the method must contain PE.

state of the prior art and unpredictability

There does not appear to be any prior art directed to the intended determination of propensity of patient risk for thrombotic disease or determination of antibodies which selectively block the action of oxidized lipids.

Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and limited number of working examples in the specification, the nature of the invention, the state of the prior art, breadth of the claims and the unpredictability of the art.

As set forth in *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA) 1970: [Section 112] requires that the scope of the claims must bear a

reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.

In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of the enablement varies inversely with the degree of unpredictability of the factors involved. *Ex parte Humphreys*, 24 USPQ2d, 1260.

***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 9–11, 13, 18–20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Aviram *et al.* [AR].

The claims are directed to a method of comparing clotting times in the presence and absence of oxidized phospholipid reagent. The final step of the method is a mental step of concluding or determining.

Aviram *et al.* disclose a method of comparing clotting times in the presence and absence of oxidized LDL which contains phospholipids. Thus, the active steps are the same as the active steps of the instantly claimed method.

***Allowable Subject Matter***

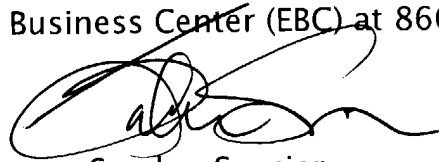
Claims 12, 21, 26–33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone

number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier  
Primary Examiner  
Art Unit 1651